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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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466	7590	10/19/2007		
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			EXAMINER HENRY, MICHAEL C	
			ART UNIT 1623	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,819	Applicant(s) MONSAN ET AL.	
	Examiner Michael C. Henry	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 22-42 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03/14/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 22-42 are pending in application

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

A written description analysis involves three principle factors:

- (1) field of the invention
- (2) breath of the claims, and
- (3) possession of the claimed invention at the time of filing for each claimed

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species/genus based upon the teachings of the specification and the field of the invention.

The Federal Circuit court stated that written description of an invention "requires a precise definition, such as by structure, formula, or chemical name, of the claimed subject matter sufficient to distinguish it from other material". *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed Cir. 1997). The court also stated "Naming a type of material generally known to exist, in the absence as to what the material consists of is not a definition of that material". *Id.* Further, the court stated that to adequately describe a claimed genus, adequate must describe a representative number of species of the claimed genus, and that one skilled in the art should be able to "visualize or recognize the identity of the members of the genus". *Id.*

(A) Provide a brief backdrop of the field of the invention. A reference from the BACKGROUND might very well be sufficient.

(B) Outline the scope and content of the claims briefly

(C) At the time of filing, from the disclosure, does it appear applicants were indeed in possession of the claimed invention?

The claims are drawn to a method of treatment and/or of prevention of hyperglycemic syndromes and in particular of treatment of type II diabetes and/or of prevention of the appearance of a type II diabetes in subjects presenting a predisposition to develop this type of diabetes, namely in subjects presenting clinical signs predictive of this diabetes, such as a decrease in glucose tolerance, or sensitivity to insulin, in particular in subjects presenting a hereditary predisposition to develop this type of diabetes, or linked to their eating habits, said subjects suffering from obesity, or being at risk of becoming obese, comprising administering an appropriate amount of one or more prebiotics. The examiner notes that the knowledge and level of skill in this art would not permit one skilled in this art to assert a preventive therapeutic mode

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of administration and the skilled artisan could not immediately envisage the invention claimed. Applicant claims are drawn to a method of prevention of hyperglycemic syndromes and prevention of the appearance of a type II diabetes in subjects presenting a predisposition to develop this type of diabetes, which is not generally known to exist in this art; additionally, the disclosure is silent with regard to that which makes up and identifies the claimed method for preventing the said disease or condition, which is seen to be lacking a clear description via art recognized procedural and methodological steps. First, the said compositions do not prevent diabetes or obesity much less hyperglycemic syndromes (e.g., obese-hyperglycemic syndrome). The prevention of the said disease or condition is not enabled since each disease (diabetes, obesity or hyperglycemic syndromes) does not have a single recognized cause and there are different types of diabetes or obesity. In fact, the aforementioned disease is recognized as having many contributing factors, ranging from hereditary considerations, to lifestyles choices such as the diet and maintenance of bodily healthiness which includes (1) high blood sugar (2) high cholesterol (3) eating habits and (4) family history of obesity disease or diabetes. These are only a few of the factors that promote these diseases in people. Also, there are several types of hyperglycemic syndromes such as obese hyperglycemic syndrome, hyperosmolar hyperglycemic syndrome, spontaneous hyperglycemic syndromes and genetic hyperglycemic syndrome. Furthermore, as example, there are various forms of obesities or obese hyperglycemic syndrome which involve different etiologies and pathologies and depends on several factors such as genetic, traumatic and environmental factors. Applicant has not provided a description as how any cause (like the aforementioned) can be prevented, much less a description of how the said disease can be prevented. Furthermore, Applicant has not provided

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any clear description via art recognized procedural and methodological steps. Moreover, Applicant has not provided an adequate representation of the mode of treatment of said diseases to provide a full, clear and precise indication that applicant is in possession of the members of the methodological and procedural steps which would enable the skilled artisan to practice this invention by said diseases. It should be noted that claims 29-34 which are drawn to a composition for preventing hyperglycemic syndromes and diabetes are also encompassed by the aforementioned rejection since said composition cannot be used to prevented said hyperglycemic syndromes and diabetes as set forth above.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-34 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites “a method of treatment and/or of prevention of hyperglycemic syndromes and in particular of treatment of type II diabetes” However, the claim is indefinite and confusing since type II diabetes is not a hyperglycemic syndrome but hyperglycemic syndrome such as Hyperglycemic Hyperosmolar Nonketotic Syndrome (HHNS) can possible occurs in people with mild or undiagnosed type 2 diabetes. Thus, for example, it is confusing and unclear whether applicant’s invention treats type II diabetes wherein a hyperglycemic syndrome (such as Hyperglycemic Hyperosmolar Nonketotic Syndrome (HHNS)) does not occur. Also, the phrase “in particular” in line 2 of the claim renders the claim

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indefinite since it is unclear whether or not applicant's method is for the treatment of type II diabetes or for hyperglycemic syndrome especially since type II diabetes is not considered a hyperglycemic syndrome. Also, the phrase "in particular" seems to indicate that applicant's method may or may not be for the specific treatment of type II diabetes only. Furthermore, the phrase "in particular" in line 7 of the claim appears to indicate that applicant's method may or may not be intended for specific subjects only. Similarly, as explained in the foregoing the phrase "in particular" in claim 29 renders the claims indefinite.

Claim 22 recites the phrase "an appropriate amount". However, the claim is indefinite because it is unclear what amount or quantity constitutes "an appropriate amount".

Regarding claims 22, 25, 29 and 32, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 27, 34 and 40 recite the phrases "disaccharides (maltose, leucrose, sacharose)" and "trisaccharides (panose, maltotriose)". However, the claims are indefinite since it is unclear whether or not the disaccharides and trisaccharides referred to are only those that are enclosed in parentheses.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 29, 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyake et al. (US 4,518,581).

In claim 29, applicant claims a food composition, nutritional additive, functional food or nutraceutical, comprising one or more prebiotics, and intended for the nourishment of subjects suffering from hyperglycemic syndrome and/or at risk of developing this syndrome, in the context of the treatment and/or the prevention of hyperglycemic syndromes, and in particular for the nourishment of subjects suffering from type II diabetes in the context of the treatment of this pathology and/or for the nourishment of subjects suffering from obesity, or at risk of becoming obese, and presenting a predisposition to develop this type of diabetes, namely in subjects presenting clinical signs predictive of this diabetes, such as a decrease in glucose tolerance, or sensitivity to insulin, in particular in subjects presenting a hereditary predisposition to develop this type of diabetes, or linked to their eating habits, in the context of preventing the appearance of a type II diabetes in these subjects. Miyake et al. disclose applicant's food composition comprising isomaltotriose (see col. 13, example 18, lines 12-30). Claims 32-34 which are drawn to the food composition wherein the prebiotics are specific oligosaccharides including glucooligosaccharides and glucooligosaccharides of specific composition are anticipated by Miyake et al.'s since Miyake et al.'s food composition also contains the same glucooligosaccharides (see col. 13, example 18, lines 12-30). It should be noted that it is well settled that "intended use" of a composition or product, e.g., for the nourishment of subjects, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

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Claims 35, 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Letellier et al. (Canadian Journal of Veterinary Research = Revue Canadienne de Recherche Veterinaire, (2000 Jan) Vol. 64, No. 1, pp. 27-31) (Abstract Only).

In claim 35, applicant claims a pharmaceutical composition characterized in that it comprises one or more prebiotics in combination with a pharmaceutically acceptable vehicle. Letellier et al. disclose applicant's composition characterized in that it comprises a prebiotics (fructooligosaccharides) in combination with a pharmaceutically acceptable vehicle (water) (see abstract). Claim 41 is drawn to said composition wherein the composition is in a form which can be administered by oral route. Letellier et al. disclose applicant's composition characterized in that it comprises a prebiotics (fructooligosaccharides) in combination with a pharmaceutically acceptable vehicle (water) that is suitable for oral administration (see abstract). Claim 42 is drawn to said composition wherein the composition is administered at specific dosage or dosage rate. Letellier et al. disclose applicant's composition characterized in that it comprises prebiotics (fructooligosaccharides) in combination with a pharmaceutically acceptable vehicle (water) (see abstract). It should be noted that the claim is a composition or product claim and thus the rate of which the composition is administered does not further limit composition claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 22-25, 28-32, 35-38, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberfroid et al. (Annual Review of Nutrition, (1998) vol. 18, pp. 117-43).

In claim 22, applicant claims a method of treatment and/or of prevention of hyperglycemic syndromes and in particular of treatment of type II diabetes and/or of prevention of the appearance of a type II diabetes in subjects presenting a predisposition to develop this type of diabetes, namely in subjects presenting clinical signs predictive of this diabetes, such as a decrease in glucose tolerance, or sensitivity to insulin, in particular in subjects presenting a hereditary predisposition to develop this type of diabetes, or linked to their eating habits, said subjects suffering from obesity, or being at risk of becoming obese, comprising administering an appropriate amount of one or more prebiotics. Claims 23-25, 28 are drawn to the method of claim 22 wherein the prebiotics are non-indigestible oligosaccharides are of specific degree of polymerization, specific oligosaccharides including fructooligosaccharide and wherein the prebiotics are administered at specific dosage.

Roberfroid et al. disclose that inulin-type fructans can be used to treat non-insulin dependent diabetes (type II diabetes) and obesity (see abstract). Furthermore, Roberfroid et al. disclose the inulin-type fructans or fructooligosaccharides $G_{py}F_n$ (α -D-glucopyranosyl- $[\beta$ -D-fructofuranosyl] $_{n-1}$ -D-fructofuranoside) and $F_{py}F_n$ (β -D-fructopyranosyl- $[\beta$ -D-fructofuranosyl] $_{n-1}$ -D-fructofuranoside) (see page 119, 2nd paragraph and figure 1). Roberfroid et al. disclose that n (the number of β -D-fructofuranose units or the degree of polymerization) is from 2 to 70 (see page 119, 2nd paragraph and figure 1). It should be noted that in the $G_{py}F_n$ inulin-type fructan or oligosaccharide the linkage between the O- α -D-glucopyranosyl unit and the D-fructofuranosyl unit is (1 \rightarrow 2) and is also (1 \rightarrow 2) between the [O- β -D-fructofuranose units (see page 119, figure 1).

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That is, the inulin-type fructan or oligosaccharide compound $G_{py}F_n$ can represent a compound of the general formula $O-\alpha-D\text{-glucopyranosyl}-(1\rightarrow 2)-[O-\beta-D\text{-fructofuranosyl}-(1\rightarrow 2)]_n$ for example, when $n = 4$ (see page 119, figure 1). Also, Roberfroid et al. disclose that the $G_{py}F_n$ compounds can be used in food industry (see page 120, 1st paragraph).

The difference between applicant's claimed method and the method taught by Roberfroid et al. is that Roberfroid et al. do not treat diabetes or obesity with the $G_{py}F_n$ inulin-type fructan or oligosaccharide per se. However, Roberfroid et al. suggest that the inulin-type fructan or oligosaccharide $G_{py}F_n$ can be used to treat non-insulin dependent diabetes (type II diabetes) and obesity (see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have treated diabetes or obesity in a subject with the $G_{py}F_n$ inulin-type fructan or oligosaccharide suggested by Roberfroid et al.

One having ordinary skill in the art would have been motivated to treat diabetes or obesity in a subject with the $G_{py}F_n$ inulin-type fructan or oligosaccharide suggested by Roberfroid et al., since Roberfroid et al. suggest that it can be used and based on factors such as need and/or availability. It should be noted that the use of specific dosage depends on factors such as the severity of the diabetes or obesity and the type, weight and age of the individual treated.

In claim 29, applicant claims a food composition, nutritional additive, functional food or nutraceutical, comprising one or more prebiotics, and intended for the nourishment of subjects suffering from hyperglycemic syndrome and/or at risk of developing this syndrome, in the context of the treatment and/or the prevention of hyperglycemic syndromes, and in particular for

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the nourishment of subjects suffering from type II diabetes in the context of the treatment of this pathology and/or for the nourishment of subjects suffering from obesity, or at risk of becoming obese, and presenting a predisposition to develop this type of diabetes, namely in subjects presenting clinical signs predictive of this diabetes, such as a decrease in glucose tolerance, or sensitivity to insulin, in particular in subjects presenting a hereditary predisposition to develop this type of diabetes, or linked to their eating habits, in the context of preventing the appearance of a type II diabetes in these subjects. Claims 30-32 are drawn to the food composition of claim 29 wherein the prebiotics are non-indigestible oligosaccharides of specific degree of polymerization, specific oligosaccharides including fructooligosaccharide and wherein the prebiotics are administered at specific dosage. Claim 35 is drawn to a pharmaceutical composition characterized in that it comprises one or more prebiotics in combination with a pharmaceutically acceptable vehicle. Claims 36-38, 41 and 42 are drawn to the method of claim 35 wherein the prebiotics are non-indigestible oligosaccharides of specific degree of polymerization, specific oligosaccharides including fructooligosaccharide and wherein the prebiotics are suitable for specific form of administration and are administered at specific dosage.

Roberfroid et al. disclose the inulin-type fructans or fructooligosaccharides $G_{py}F_n$ (α -D-glucopyranosyl- $[\beta$ -D-fructofuranosyl] $_{n-1}$ -D-fructofuranoside) and $F_{py}F_n$ (β -D-fructopyranosyl- $[\beta$ -D-fructofuranosyl] $_{n-1}$ -D-fructofuranoside) (see page 119, 2nd paragraph and figure 1). Roberfroid et al. disclose that n (the number of β -D-fructofuranose units or the degree of polymerization) is from 2 to 70 (see page 119, 2nd paragraph and figure 1). It should be noted that in the $G_{py}F_n$ inulin-type fructan or oligosaccharide the linkage between the O- α -D-

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glucopyranosyl unit and the D-fructofuranosyl unit is (1→2) and is also (1→2) between the [O-β-D-fructofuranose units (see page 119, figure 1). That is, the inulin-type fructan or oligosaccharide compound $G_{py}F_n$ can represent a compound of the general formula O-α-D-glucopyranosyl- (1→2)-[O-β-D-fructofuranosyl-(1→2)]_n for example, when n = 4 (see page 119, figure 1). Furthermore, Roberfroid et al. disclose that inulin-type fructans can be used to treat non-insulin dependent diabetes (type II diabetes) and obesity (see abstract). Also, Roberfroid et al. disclose that the $G_{py}F_n$ compounds can be used in food industry (see page 120, 1st paragraph). It should be noted that it is well settled that “intended use” of a composition or product, e.g., for the nourishment of subjects, does not further limit claims drawn to a composition or product. See, e.g., *Ex parte Marsham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

The difference between applicant's claimed method and the method taught by Roberfroid et al. is that Roberfroid et al. do not prepare a food composition comprising the $G_{py}F_n$ inulin-type fructan or oligosaccharide per se. However, Roberfroid et al. suggest that the inulin-type fructan or oligosaccharide $G_{py}F_n$ can be used in the food industry (i.e., as food composition) (see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared a food composition comprising the $G_{py}F_n$ inulin-type fructan or oligosaccharide suggested by Roberfroid et al. to treated diabetes or obesity in a subject.

One having ordinary skill in the art would have been motivated to prepare a food composition comprising the $G_{py}F_n$ inulin-type fructan or oligosaccharide suggested by Roberfroid et al. to treated diabetes or obesity in a subject, based on factors such as need and/or

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availability. It should be noted that the use of specific dosage depends on factors such as the severity of the diabetes or obesity and the type, weight and age of the individual treated. It should be noted claims 35-38, 41 and 42 which are drawn to a pharmaceutical composition characterized in that it comprises one or more prebiotics in combination with a pharmaceutically acceptable vehicle are also obvious over Roberfroid et al.'s as set forth above since it is common in the art and well within the purview of a skilled artisan to combine pharmaceutical compositions such as Roberfroid et al.'s oligosaccharide composition with a pharmaceutically acceptable vehicle in order to use it to treat disorders or conditions such as diabetes and obesity.

Claims 22, 25-28, 35, 38, 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiji (US 4,913,925).

In claim 22, applicant claims a method of treatment and/or of prevention of hyperglycemic syndromes and in particular of treatment of type II diabetes and/or of prevention of the appearance of a type II diabetes in subjects presenting a predisposition to develop this type of diabetes, namely in subjects presenting clinical signs predictive of this diabetes, such as a decrease in glucose tolerance, or sensitivity to insulin, in particular in subjects presenting a hereditary predisposition to develop this type of diabetes, or linked to their eating habits, said subjects suffering from obesity, or being at risk of becoming obese, comprising administering an appropriate amount of one or more prebiotics. Claims 25-28 are drawn to the method of claim 22 wherein the prebiotics are specific oligosaccharides including glucooligosaccharides, glucooligosaccharides of specific composition and wherein the prebiotics are administered at specific dosage.

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Hiji discloses that isomaltotriose which is an oligosaccharide (i.e., a glucooligosaccharide) consisting of three glucose molecules bonded by .alpha.-1,6-bonds, is a hyperglycemia controlling agent which can control or inhibit the increase in blood sugar content in order to prevent obesity in a normal person or to implement the diet therapy of a diabetic person (col. 1, lines 15-34).

The difference between applicant's claimed method and the method taught by Hiji is that Hiji does not treat obesity or diabetes with isomaltotriose per se. However, Hiji discloses that isomaltotriose can be used to treat diabetes and obesity (col. 1, lines 15-34).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have treated obesity or diabetes in a subject with the glucooligosaccharide isomaltotriose as by suggested by Hiji.

One having ordinary skill in the art would have been motivated to treat obesity or diabetes in a subject with the glucooligosaccharide, isomaltotriose, since Hiji suggests that it can be used and based on factors such as need and/or availability. It should be noted that the use of specific dosage depends on factors such as the severity of the obesity or diabetes and the type, weight and age of the individual treated.

In claim 35, applicant claims a pharmaceutical composition characterized in that it comprises one or more prebiotics in combination with a pharmaceutically acceptable vehicle. Claims 38, 39-42 are drawn to said composition wherein the prebiotics are specific oligosaccharides including glucotooligosaccharide and wherein the prebiotics are suitable for specific form of administration and are administered at specific dosage.

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Hiji discloses that isomaltotriose (prebiotic) which is an oligosaccharide (i.e., a glucooligosaccharide) consisting of three glucose molecules bonded by α -1,6-bonds, is a hyperglycemia controlling agent which can control or inhibit the increase in blood sugar content in order to prevent obesity in a normal person or to implement the diet therapy of a diabetic person (col. 1, lines 15-34).

The difference between applicant's claimed composition and the composition taught by Hiji is that Hiji's composition does not contain a pharmaceutically acceptable vehicle. However, it is common in the art and well within the purview of a skilled artisan to combine pharmaceutical compositions such as Hiji's oligosaccharide composition with a pharmaceutically acceptable vehicle in order to use it to treat disorders or conditions such as diabetes and obesity.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have treated obesity or diabetes in a subject with the glucooligosaccharide isomaltotriose in combination with a pharmaceutically acceptable vehicle such as water since it common in the art and well within the purview of a skilled artisan to combine pharmaceutical compositions such as Hiji's oligosaccharide composition with a pharmaceutically acceptable vehicle in order to use it to treat disorders or conditions such as diabetes and obesity

One having ordinary skill in the art would have been motivated to treat obesity or diabetes in a subject with the glucooligosaccharide, isomaltotriose, and to use a pharmaceutically acceptable vehicle such as water since it common in the art and well within the purview of a skilled artisan to combine pharmaceutical compositions such as Hiji's oligosaccharide composition with a pharmaceutically acceptable vehicle in order to use it to treat disorders or conditions such as diabetes and obesity, based on factors such as need and/or availability. It

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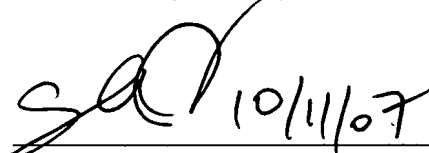
should be noted that the preparation or use of specific dosage depends on factors such as the severity of the obesity or diabetes and the type, weight and age of the individual treated.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry


Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

October 5, 2007.